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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 315 and 601

[Docket No. 98D-0785]

**Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics;
Availability; Reopening of Comment Period**

AGENCY: Food and Drug Administration, HHS.

ACTION: Availability of guidance; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until February 12, 1999, the comment period for the draft guidance for industry entitled "Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics" that appeared in the **Federal Register** of October 14, 1998 (63 FR 55067). FDA is taking this action in response to a request for an extension.

DATES: Written comments on the draft guidance may be submitted by February 12, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448, FAX 888-CBERFAX or 301-827-3844. Send two self-addressed adhesive labels to assist the office in processing your request. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration,

5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Robert K. Leedham, Center for Drug Evaluation and Research (HFD-160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7510, or

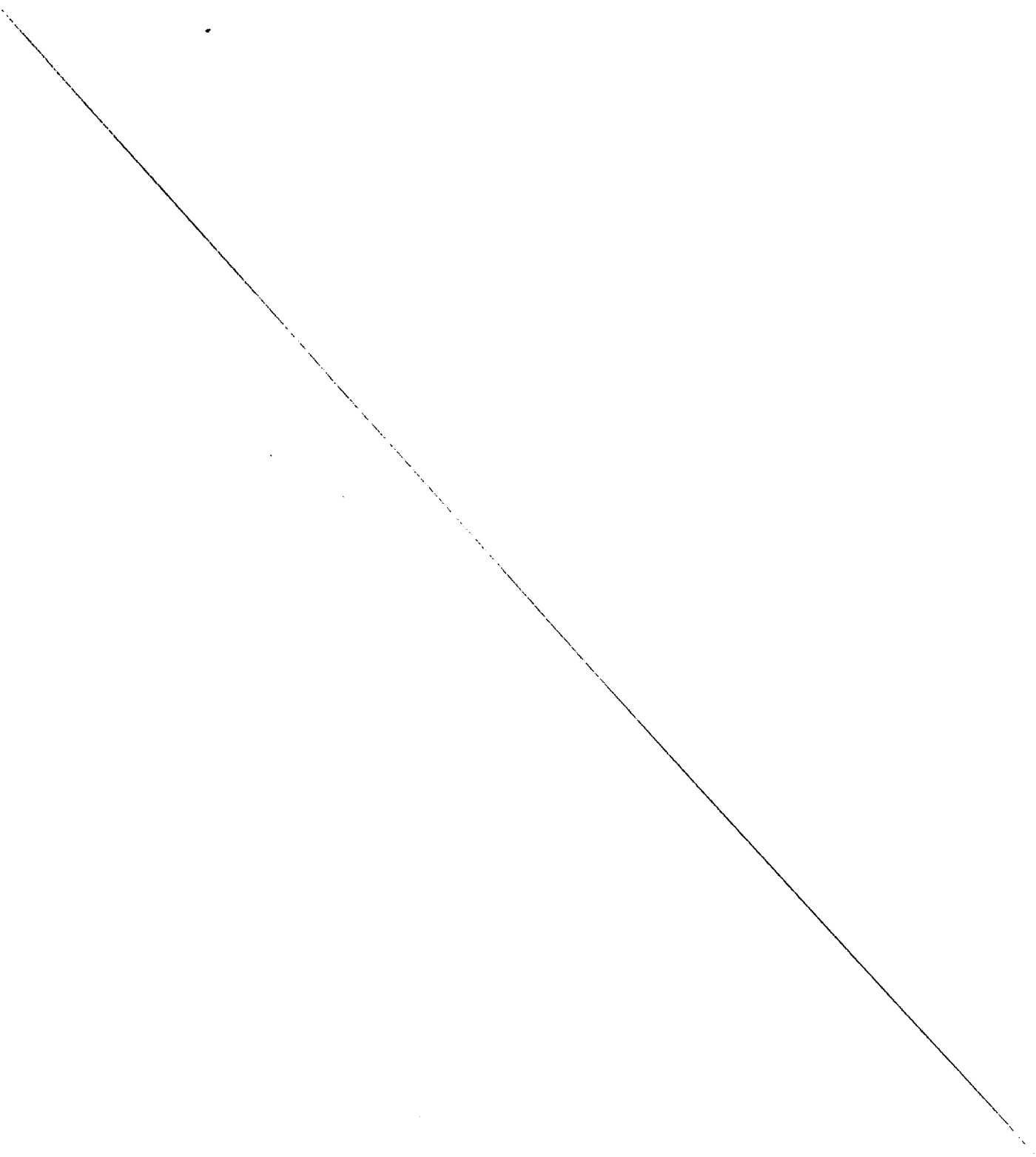
George Q. Mills, Center for Biologics Evaluation and Research (HFM-573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-5097.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 14, 1998 (63 FR 55067), FDA published a notice announcing the availability of a draft guidance document for industry entitled “Developing Medical Imaging Drugs and Biologics.” The draft guidance is intended to assist developers of drug and biological products used for medical imaging, as well as radiopharmaceutical drugs used in disease diagnosis, in planning and coordinating the clinical investigations of, and submitting various types of applications for, such products. The draft guidance also provides information on how the agency would interpret and apply provisions in proposed regulations, published in the **Federal Register** of May 22, 1998 (63 FR 28301), for in vivo radiopharmaceuticals used for diagnosis and monitoring. The draft guidance applies to medical imaging drugs that are used for diagnosis and monitoring and that are administered in vivo. The draft guidance is not intended to apply to possible therapeutic uses of these drugs or to in vitro diagnostic products. Interested persons were given until December 14, 1998, to submit written comments on the draft guidance.

FDA received a letter, dated December 4, 1998, from Alan M. Kirschenbaum, legal counsel for the Council on Radionuclides and Radiopharmaceuticals, requesting that the agency extend the comment period on the draft guidance by 60 days.

The draft guidance introduces several new and highly technical issues. Therefore, the agency has decided to reopen the comment period on the draft guidance until February 12, 1999, to allow the public more time to review and comment on its contents.

Interested persons may, on or before February 12, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to



be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 28, 1998

December 28, 1998



William K. Hubbard
Associate Commissioner for Policy Coordination

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